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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,780	07/01/2003	Michael W. Dae	RADNT-039C	5891

7590 01/04/2005  
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EXAMINER

GIBSON, ROY DEAN

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 01/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/612,780

Applicant(s)

DAE ET AL.

Examiner

Roy D. Gibson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-34, 40-48, 51 and 52 is/are rejected.
- 7) ☐ Claim(s) 35-39, 49 and 50 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 July 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/01/2003</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Drawings***

The drawings are objected to because in Figure 17, in block 2, "exchange" is misspelled. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re*

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*Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-34, 40, 41, 51 and 52 rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-20, 25-42 and 49 of prior U.S. Patent No. 6,685,733.

This is a double patenting rejection.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 44 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 44 recites the limitation "the at least one balloon" in line 1. There is insufficient antecedent basis for this limitation in the claim. The examiner suggests this claim should depend from claim 43 to correct this.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 42-46 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Ginsburg (5,837,003).

As to claims 42-44, Ginsburg discloses a system comprising:

a heat exchange catheter insertable into a blood vessel of a patient; and a temperature controller in communication with the heat exchange catheter to reduce the temperature of a patient's organ as required, wherein the heat exchange catheter comprises a balloon (Figure 9) containing a heat exchange fluid flowing from the temperature controller and wherein the balloon is circumferentially disposed about the catheter (col. 3, line 44-col. 5, line 38 and col. 5, line 49-col. 6, line 31).

As to claims 45, 46 and 48, Ginsburg further discloses the temperature controller includes temperature monitoring means and adjusting means for adjusting the temperature of the heat exchange catheter to maintain a constant reduced temperature of the patient's organ, wherein the adjusting is in response to the monitored temperature and wherein the controller controls the temperature and flow of heat exchange fluid flowing through the heat exchange catheter (col. 3, line 44-col. 5, line 38 and col. 5, line 49-col. 6, line 31).

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 42 and 45-48 are rejected under 35 U.S.C. 102(e) as being anticipated by Dobak, et al. (6,096,068). Dobak et al. disclose all elements as claimed including the

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limitation of a heat exchange catheter comprising a flow disruption device (Figure 7) to disrupt the laminarity of blood flow around the catheter (col. 1, lines 17-33, col. 2, line 66-col. 3, line 40, col. 4, lines 17-52, col. 6, line 10-col. 7, line 4, col. 10, lines 37-59 and col. 16, line 25-col. 17, line 18).

Claims 42-48 are rejected under 35 U.S.C. 102(e) as being anticipated by Balding et al. (6,572,640). Balding discloses all elements as claimed (Figures 2A, 2B and 4 and col. 3, line 44-col. 5, line 38, and col. 5, line 49-col. 6, line 31).

### ***Allowable Subject Matter***

Claims 35-39, 49 and 50 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Conclusion***

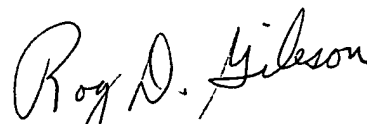
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Noda et al. (6,530,946) disclose an indwelling heat exchange catheter with a balloon which anticipates claims 42-46 and 48; Pham et al. (6,299,599) disclose a dual balloon catheter temperature control system which anticipates claims 42-46 and 48; Gobin et al. (6,126,684) disclose an indwelling heat exchange catheter which anticipates claims 42-46 and 48.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy D. Gibson whose telephone number is 571-272-4767. The examiner can normally be reached on M-F, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Roy D. Gibson  
Primary Examiner  
Art Unit 3739

December 28, 2004